Ortho-Clinical Diagnostics
a Johnson & Johnson company

DEC 1 ɔ 2006

100 Indigo Creek Drive
Rochester, New York 14626-5101

5.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K062460

1. **Submitter name, address, contact**

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-4041
Contact Person: Marlene Hanna

2. **Preparation Date**

August 22, 2006

3. **Device name**

Trade or Proprietary Names:
VITROS Chemistry Products OP Reagent
VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V

Common Names:
Opiates assay and controls

Classification Names:
1. Opiate test system (21 CFR 862.3650) Class II
2. Clinical toxicology calibrators (21 CFR 862.3200) Class II
3. Clinical toxicology control material (21 CFR 862.3280) DAT Performance Verifiers I, II ,III, IV, and V) are assayed controls, so they meet the reserved criteria under Section 510(l) of the Food, Drug, and Cosmetic Act.

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4. Predicate Devices

The VITROS Chemistry Products OP assay is substantially equivalent to the EMIT® II Plus Opiate assay.

The VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the Bio-Rad Liquicheck™ UrineToxicology Controls.

5. Device description

The VITROS OP assay is a homogeneous enzyme immunoassay that is performed using the VITROS Chemistry Products OP Reagent with the VITROS Chemistry Products Calibrator Kit 26 and VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) on VITROS 5,1 FS Chemistry Systems. Two protocols using the VITROS OP assay are available to support the two cutoff values. The OP-LO protocol is used to support the 300 ng/mL cutoff value. The OP-HI protocol is used to support the 2000 ng/mL cutoff value.

The VITROS OP Reagent is a dual chambered package containing ready-to-use liquid reagents that are used to detect opiates in urine. Sample, calibrators, and controls are automatically treated with surfactant (DAT Diluent 2) prior to addition of reagents. Treated sample is added to Reagent 1 containing antibodies reactive to morphine, glucose-6-phosphate and nicotinamide adenine dinucleotide (NAD^+), followed by Reagent 2 containing morphine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH). The assay is based on competition between opiates in the treated urine sample and the morphine labeled with the enzyme glucose-6-phosphate dehydrogenase (G6P-DH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, therefore the concentration of opiates in the urine sample is directly proportional to measured enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD^+) to NADH, resulting in an absorbance change that is measured spectrophotometrically at 340 nm.

The VITROS Chemistry Products Calibrator Kit 26 is prepared from human urine to which drugs of abuse, metabolites of drugs of abuse, organic salt, surfactants, and preservative have been added. VITROS Calibrator Kit 26 is a single fluid and from it six dilutions are performed on the VITROS 5,1 FS Chemistry System to create a total of six calibrators. These standards are used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative and semi-quantitative measurement of Opiates (OP).

The VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V are quality control materials prepared from a human urine pool to which analytes, surfactant, and preservative have been added. These are assayed controls used to monitor performance of the VITROS OP assay on VITROS 5,1 FS Chemistry Systems.

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The VITROS Chemistry Products FS Diluent Pack 4 (DAT Diluent / DAT Diluent 2) is a common reagent that is used by multiple assays on the VITROS 5,1 FS Chemistry System. This is a dual chambered package containing two ready-to-use liquid diluents. DAT Diluent is prepared from human urine to which organic salt, surfactants, and preservative have been added. DAT Diluent 2 is prepared from processed water to which surfactant and preservative have been added.

The VITROS 5,1 FS Chemistry System is a clinical chemistry instrument that provides automated use of the VITROS Chemistry Products MicroTip® and MicroSlides® range of products. The VITROS 5,1 FS System was cleared for market by 510(k) premarket notification (K031924).

6. Device intended uses

VITROS Chemistry Products OP Reagent: For *in vitro* diagnostic use only. VITROS Chemistry Products OP Reagent is used on VITROS 5,1 FS Chemistry Systems for the semi-quantitative or qualitative determination of opiates (OP) in human urine using a cutoff of either 300 ng/mL or 2000 ng/mL. Measurements obtained with the VITROS OP method are used in the diagnosis and treatment of opiate use or overdose.

The VITROS Chemistry Products OP assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

VITROS Chemistry Products Calibrator Kit 26: For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V: For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems. .

7. Comparison to predicate devices:

The VITROS Chemistry Products OP assay and VITROS Chemistry Products DAT Performance Verifiers are substantially equivalent to the EMIT® II Plus Opiate assay (K011289) and Bio-Rad Liquicheck™ Urine Toxicology Controls (K022707) predicate devices which were cleared by the FDA for IVD use.

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The performance of the VITROS OP assay on the VITROS 5,1 FS Chemistry System was compared to the EMIT® II Plus Opiate assay on the Olympus AU400 Analyzer. The results demonstrated good agreement between the two immunoassay methods.

The VITROS OP assay and VITROS DAT Performance Verifiers have the following similarities to the predicate devices: same intended use, the same cutoff values of 300 or 2000 ng/mL, are liquid, ready to use reagents, have similar performance characteristics, are used on an automated clinical chemistry analyzer and calibrated against the same drug, morphine.

Table 1 Similarities and differences of the assays performed using the VITROS OP assay and DAT controls and the EMIT® II Plus Opiate assay and Bio-Rad Urine Toxicology controls.

Device Similarities		
Device Characteristic	**Description**	
Indications for Use	For *in vitro* diagnostic use only. The assays are intended for use in the qualitative and semi-quantitative analysis of opiates in human urine. The controls are assayed controls used to monitor the performance of Chemistry Systems.	
Test Principle	Homogeneous enzyme immunoassay	
Cut-Off values	300 or 2000 ng/mL	
Specimen Type	Human Urine	
Reagent Format	Liquid ready to use	
Antibody source	Sheep polyclonal antibodies reactive to morphine	
Calibration traceability	Traceable to morphine with confirmation by GC/MS.	
Calibrator matrix	Human urine	
Control matrix	Human urine	
Device Differences		
Device Characteristic	**VITROS OP assay (New device)**	**Emit® II Plus Opiates assay (Predicate device)**
Calibrator levels	6 levels	Qualitative: Two levels Semi-quantitative: Four levels
Calibrator format	Frozen Liquid ready to use	Refrigerated liquid ready to use
Instrumentation	To be used on VITROS 5,1 FS Chemistry Systems	For use on a variety of OLYMPUS® analyzers
Controls: Drugs Reported	Cocaine metabolites (benzoylecgonine), benzodiazepines (lormetazepam), methadone, Barbiturates (secobarbital), opiates (morphine), cannabinoids (11-nor-delta-THC-9-COOH), phencyclidine and barbiturates (secobarbital).	methamphetamine, secobarbital, lormetazepam, tetrahydrocannabinol (THC), benzoylecgonine, ethanol, lysergic acid diethylamide (LSD), methadone, methaqualone, morphine, (Free), phencyclidine, propoxyphene, nortriptyline.
Controls: Number of Levels	Five	Two

8. Conclusions The data presented in the premarket notification provide a reasonable assurance that the VITROS Chemistry Products OP Reagent, VITROS Chemistry Products Calibrator Kit 26, and the VITROS Chemistry Products DAT Performance Verifiers are safe and effective for the stated intended uses and are substantially equivalent to the cleared predicate devices. Equivalence to the predicates was demonstrated using a commercially available assay along with patient samples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Marlene Hanna
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

DEC 15 2006

Re: k062460
Trade/Device Name: VITROS Chemistry Products OP Reagent
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DKB, DIF
Dated: October 4, 2006
Received: October 5, 2006

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062460

Device Name: VITROS Chemistry Products OP Reagent

Indications for Use:

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The VITROS Chemistry Products OP assay is intended for use by professional laboratory personnel. It provides only a preliminary test result. A more specific alternative chemical method must be used to confirm a result obtained with this assay. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug-of-abuse test result, particularly when evaluating a preliminary positive result.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062460

Indications for Use

510(k) Number (if known): K062460

Device Name: VITROS Chemistry Products Calibrator Kit 26
VITROS Chemistry Products DAT Performance Verifiers I, II, III, IV, and V.

Indications for Use:

For *in vitro* diagnostic use only. VITROS Chemistry Products Calibrator Kit 26 is used to calibrate VITROS 5,1 FS Chemistry Systems for the qualitative or semi-quantitative measurement of drugs of abuse.

For *in vitro* diagnostic use only. VITROS Chemistry Products DAT Performance Verifiers are assayed controls used to monitor performance of urine drugs of abuse screening assays on VITROS 5,1 FS Chemistry Systems.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K062460